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APPLICATION NO. 09/114/005001	FILING DATE 06/09/99	FIRST NAMED INVENTOR LAUTERSUNG	ATTORNEY DOCKET NO. K 09114/005001
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<b>EXAMINER</b> PREBILIC, P
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<b>ART UNIT</b> 3738	<b>PAPER NUMBER</b>
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**DATE MAILED:** 06/09/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

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08/878,908

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on January 12, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-3, 5-17, 19-26, 28, 32-36, and 47-51 is/are pending in the application.  
Of the above, claim(s) 50 and 51 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-3, 5, 6-17, 19-26, 28, 32-36, and 47-49 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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The request filed on January 12, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/878,908 is acceptable and a CPA has been established. An action on the CPA follows.

In response to the request to consider the foreign language references based upon a search report for one of the priority documents, the Examiner posits that since the search report of the priority document is based on only one of the two priority documents that it does not constitute a search report on the present application as required. For this reason, the foreign language references previously referred to have not been considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terminology "said undeformed state" (claim 2) and "said deformed state" (claim 10) now lacks antecedence.

***Claim Rejections Based on the Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Quijano et al (US 5,500,014) wherein the claims are not written in a mean plus function format for attachment to the ascending aorta. Therefore, only the structure necessary to perform the function, at most, needs to be recited. Since the Quijano et al reference discloses the use of the prosthesis on other blood vessels including pulmonary arteries and heart valves, it is the Examiner's position that the prosthesis certainly contains the structure to be used in a ascending aorta artery to the extent required by the present claims; see the entire document.

Claims 1-3, 6-9, 12-14, 16, 17, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwan-Gett (US 5,151,105) wherein the overlapping windings as claimed are met by the circular stents of Kwan-Gett elements (18) and (20) of thin flat spring material that are concentrically wound and attached together by the sutures or pockets provided by the sleeve graft; see the entire document.

With regard to claim 7 specifically, the taper is from the end section which is bulged due to the presence of the circular stents to the middle section which is not bulged to that extent; see the figures.

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Claims 12, 13, 16, 17, 19-23, 26, and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Inoue (US 5,290,305) wherein a single end ring, which constitutes an annular element as claimed, is attached to only one end of the device; see the entire document.

Claims 1-3, 5, 6, 10, 19-26, and 28 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Inoue (US 5,693,089); wherein a single end ring, which constitutes an annular element as claimed, is attached to only one end of the device; see the entire document.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue (US 5,290,305) or Inoue (US 5,693,089) in view of Porter (US 5,064,435). Inoue (both patents) meet the claim language except for the tapered or larger end of the graft as claimed. However, Porter teaches that it has been known to taper the ends of similar devices; see the figures thereof. Hence, it is the Examiner's position that it would have been obvious to taper the free ends of the graft of Inoue in order to improve the hold of the device to the vessel wall.

Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 5,064,435) in view of Inoue (US 5,290,305). Porter meets the claim language except for the tubular graft as claimed; see the entire document. However, Inoue teaches that it have been known to line similar self-expanding stents with grafts materials. Hence, it is the Examiner's

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position that it would have been obvious to surround the stents of Porter with graft material as taught by Inoue in order to prevent blood leakage in usages where leakage is harmful to the patient's health.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kwan-Gett (US 5,151,105) in view of White (WO 95/08966). Kwan-Gett meets the claim language except for the presence of a bifurcated graft as claimed. White, however, teaches that was known to modify similar stent-grafts into bifurcated or trouser grafts for the particular surgical situation involved; see page 7, lines 11-25. Hence, it is the Examiner's position that it would have been obvious to do the same to the Kwan-Gett device for the same reasons that White does the same.

#### *Response to Arguments*

Applicant's arguments filed September 3, 1998 have been fully considered but they are not persuasive.

In the traversal of the Quijano et al rejection, the Applicant posits that it teaches a natural tissue valve instead of a prosthetic heart valve as in the present claims. However, the Examiner posits that the Quijano valve is a prosthetic valve made of natural tissue. In fact, Quijano et al even calls the device thereof a "Biological Valvular Prosthesis" and even fixes the tissue change its physical and chemical form. For these reason, the Applicant's arguments are considered to be unpersuasive.

In response to the traversal that the Quijano et al reference does not disclose a ring arranged to connect the graft to the ascending aorta, the Examiner respectfully disagrees because

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the claims are not written in a mean plus function format. Therefore, only the structure necessary to perform the function, at most, needs to be recited. Since the Quijano et al reference discloses the use of the prosthesis on other blood vessels including pulmonary arteries and heart valves, it is the Examiner's position that the prosthesis certainly contains the structure to be used in an ascending aorta artery to the extent required by the present claims.

With regard to the assertion that none of the previously applied references disclose a plurality of windings of wire as set forth in present claim 1, the Examiner posits that since the claims do not require a continuous length of wire wound into a plurality of windings overlapping each other that the double ring structure of Inoue ('089) (see Figure 2, element (12a) constitutes a plurality of windings overlapping each other to the extent required. In addition, Kwan-Gett goes beyond this requirement in that it discloses a continuous length of wire wound into a plurality of windings overlapping each other.

In response to the traversal of claim 12 that it incorporates the language of claim 18, the Examiner posits that this is true to only some extent because significant portions of claim 12 have been deleted. Therefore, claim 12 does not represent claim 18 rewritten in independent form. Moreover, upon further consideration of the claim language and in view of the newly applied prior art, claim 12 is now clearly not allowable.

In response to the traversal of claim 21 that it should be allowable since it incorporates the language of claim 28, the Examiner posits that claim 28 was never indicated as containing allowable subject matter. Furthermore, a resilient element only on one end of the graft is no

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longer viewed as precluding other resilient elements from being elsewhere on the graft. For this reason, the claim is considered to be anticipated by Inoue.

Finally, in response to the traversal of claim 32, the Examiner posits that it does not address the rejection which is a combination of references and Porter alone is not required to have a graft attached to it. Inoue ('305) is utilized to teach the obviousness of using a graft on the Porter stent. For this reason, the traversal is considered to be unpersuasive.


***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

  
Paul Prebilic  
Primary Examiner  
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